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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,043	02/17/2004	Elizabeth Bates	SF0977XB	1489

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PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
DAHLE, CHUN WU	
ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/780,043	BATES ET AL.	
	Examiner	Art Unit	
	CHUN DAHLE	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05/23/2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,9,17-23 and 25-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7, 9, 17-23, and 25-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment to the claims, filed on May 23, 2008, is acknowledged.
Claims 1-6, 8, 10-16, 24, 30, and 31 have been canceled.
Claims 7, 9, 17-23, and 25-29 are pending and currently under consideration.

2. This Office Action is in response to Applicant's amendment to the claims and remarks filed on October 31, 2007.

The rejections of record can be found in the previous Office Actions, mailed on February 22, 2006, July 17, 2006, November 20, 2006, August 9, 2007, and February 5, 2008.

3. In view of applicant's cancellation of claim 31, the prior rejection against under 35 U.S.C. 112, first paragraph, written description, new matter, has been withdrawn.

4. In view of applicant's addition of the new limitation of "but does not bind a polypeptide consisting of the amino acid sequence of SEQ ID NO:2", the prior rejection under 35 U.S.C. 102(b) based on Adema et al. (WO 98/24906, cited in IDS filed 02/17/04) have been withdrawn.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 20-23 and 26-29 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention for reasons of record.

The specification as filed does not provide sufficient enabling description of the use of the claimed pharmaceutical formulation comprising an antibody to SEQ ID NO:6 for prevention, diagnosis and/or treatment of diseases in human or animals.

Applicant's arguments have been fully considered but have not been found persuasive.

Applicant argues that the rejection has been rendered moot due to the amendment of claim 7.

This is not found persuasive because the instant claims 20-23 and 26-29 still recite "a pharmaceutical formulation". Therefore, the rejection has been maintained for reasons of record set forth in previous Office Action mailed on February 5, 2008.

7. This is a **New Ground of Rejection.** Claims 7, 9, 17-23 and 25-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a *Written Description*, New Matter rejection.

The phrase "but does not bind a polypeptide consisting of the amino acid sequence of SEQ ID NO:2" recited in claims 7, 9, 17-23, and 25-29 are not supported by the original disclosure or claim as filed.

Applicant's arguments have been fully considered but have not been found persuasive.

Applicant argues that the instant specification discloses that human receptor proteins including FDF03 (SEQ ID NO:2) and FDF03-S1 (SEQ ID NO:6) represent activation isoforms of FDF03 receptor and could be used as population markers (see lines 11-14 on page 11 of the instant specification). Applicant further argues that the specification discloses that antibodies could be used as probes to distinguish tissue and cell type distribution (see lines 5-19 on page 21 of the instant specification). Therefore, applicant asserts one of skill in the art would understand that the inventors are in possession of antibodies that specifically bind to each disclosed receptor homologs but do not bind FDF03 receptor or other homologs. Furthermore, applicant argues that based on the disclosure, one skilled artisan would be able to make antibodies that bind FDF03-S1 (SEQ ID NO:6) but does not bind FDF03 (SEQ ID NO:2).

This is not found persuasive for reasons of record set forth in previous Office Action mailed on August 9, 2007.

In addition, it appears that different isoforms of the proteins can bind the same ligand (e.g. see 3rd paragraph on page 11 of the instant specification). Given that antibody that binds the claimed polypeptide can be considered as ligand, it does not appear that the specification discloses any antibody that binds one polypeptide but does not bind other polypeptides. Therefore, the specification does not describe an antibody that specifically binds polypeptide of SEQ ID NO:6 "but does not bind a polypeptide consisting of the amino acid sequence of SEQ ID NO:2" in such a way as to reasonably convey to one skilled in the art that applicant had in possession of the claimed antibody at the time of the invention.

Further, in contrast to applicant's reliance on that one skill in the art is enable to make antibodies that bind FDF03-S1 (SEQ ID NO:6) but does not bind FDF03 (SEQ ID NO:2), it is noted that rejection is based upon the lack of written description (new matter), not enablement. Thus, applicant's arguments have not been found persuasive. The adequate written description requirement, which is distinct from the enablement and best mode requirements, serves "to ensure that the inventor had possession, as of the filing date of the application relied on, of the

specific subject matter later claimed by him; how the specification accomplishes this is not material." In re Wertheim, 262, 191 USPQ 90 (CCPA 1976). In order to meet the adequate written description requirement, the applicant does not have to utilize any particular form of disclosure to describe the subject matter claimed, but "the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." In re Gosteli , 872 F.2d 1008 , 1012, 10 USPQ2d 1614 (Fed.Cir. 1989). Put another way, "the applicant must . . . convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention ." Vas-Cath , 935 F.2d at 1563-64, 19 USPQ2d at 1117 .

Once again, the specification does not provide sufficient support for "but does not bind the polypeptide consisting of the amino acid sequence of SEQ ID NO:2". The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is once again required to cancel the new matter in the response to this Office Action.

Applicant is reminded that if the new matter "but does not bind a polypeptide consisting of the amino acid sequence of SEQ ID NO:2" is canceled, the withdrawn rejection under 35 U.S.C. 102(b) based on Adema et al. (WO 98/24906, cited in IDS filed 02/17/04) may be reinstated.

8. Claims 7, 9, 17-23, and 25-29 stand rejected under 35 U.S.C. 102(e) as being anticipated by Lal et al. (US Patent Application 2005/0155089, reference on PTO-892 mailed on August 9, 2007) as evidenced by Campbell (Monoclonal Antibody Technology. 1985 Published by Elsevier Science Publishers. Chapter I, pages 1-32, of record) for reasons of record.

The previous Office Action mailed on August 9, 2007 states:

"Lal et al. teach human signal peptide containing proteins including proteins with amino acid sequence of SEQ ID NO:7 that is 100% identical to the instant SEQ ID NO:6 (see paragraph [0041] and attached sequence alignment, in particular). Lal et al. further teach purified antibodies that bind human signal peptide containing protein of SEQ ID NO:7 including monoclonal antibodies, antibody fragments such as Fab, Fv, recombinant antibody, e.g. humanized antibody or fragment thereof, and hybridoma that produces antibodies (see entire document, particular paragraphs [0074] and [0144]-[0153]). Furthermore, Lal et al. teach a pharmaceutical composition, comprising said antibodies and pharmaceutically acceptable carriers, suitable for parenteral administration including subcutaneous or intravenous administration (e.g. see paragraphs [0168]-[0183])."

Applicant's arguments in conjunction with various legal citations have been fully considered but have not been found persuasive.

Applicant argues that Lal et al. does not teach specific and substantial utility for polypeptide of SEQ ID NO:7 that is 100% identical to the instant SEQ ID NO:6. Therefore, applicant asserts that Lal et al. is not an appropriate prior art to be relied upon for rejection under35 U.S.C. 102(e) because Lal et al. do not provide sufficient teachings to enable skilled artisan. Applicant further asserts that Lal et al. only teach that the peptides including SEQ ID NO:7 can be used in general to diagnose, treat, or prevent disorders; however, the disclosed utility is not specific or substantial and would not meet the enablement requirement.

This is not found persuasive for reasons of record set for the in previous Office Action mailed on February 5, 2008.

Further, in contrast to applicant's assertion that In re Hafner only apply to rejection under 35 U.S.C. 102(b), not 102(e), it is noted that the In re Hafner is applicable to the principle of anticipation regardless under 102(b) or 102(e).

Furthermore, contrary to applicant's argument that Lal et al. cannot be used as 102(e) type of art because the polypeptides taught by Lal et al. lack utility, it is noted that in order to constitute anticipatory prior art, a reference must identically disclose the claimed compound, but no utility need be disclosed by the reference. In re Schoenwald, 964 F.2d 1122, 22 USPQ2d 1671 (Fed. Cir. 1992); the court explained that "no utility need be disclosed for a reference to be anticipatory of a claim to an old compound." 964 F.2d at 1124, 22 USPQ2d at 1673. It is enough that the claimed compound is taught by the reference.). See also Impax Labs. Inc. v. Aventis Pharm. Inc., 468 F.3d 1366, 1383, 8 USPQ2d 1001, 1013 (Fed. Cir. 2006) and also see MPEP 2122.

Here, Lal et al. teach antibody to polypeptide with amino acid sequence of SEQ ID NO:7 that is 100% identical in amino acid sequence to the instant claimed SEQ ID NO:6. Therefore, no utility need be disclosed for Lal et al. to be anticipatory of the claimed antibody.

Moreover, as stated in previous Office Action mailed on February 5, 2008, the methods of making antibody were well known and considered routine in the art at the time of invention. For example, Campbell teaches methods of making antibodies and the advantages of using antibodies e.g. monoclonal antibody in basic research, diagnostics and therapeutic uses (see entire document, particularly pages 2-23). Further, Campbell teaches that it is customary now for any group working on macromolecule to both clone the genes coding for it and make monoclonal antibodies to it, sometimes without a clear objective for their application (e.g. see page28).

Therefore, applicant's arguments have not been found persuasive.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 7 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lal et al. (US Patent Application 2005/0155089, reference on PTO-892 mailed on August 9, 2007) in view of Markussen (US Patent 5,317,092, reference on PTO-892 mailed on August 9, 2007) for reasons of record.

The rejection of record is to address the limitation of "bound to a solid support" as recited in claim 19.

Applicant's arguments have been fully considered but have not been found persuasive.

Applicant's arguments and the Examiner's rebuttal are essentially the same as discussed above.

Given the teachings of Lal et al. providing the uses of antibody in various immunoassys and the teachings of Markussen regarding method of using antibody immobilized to a solid support, the ordinary artisan at the time the invention was made would have had a reasonable expectation of success of producing the claimed antibody or fragment thereof that is bound to a solid support.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. Conclusion: no claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Dahle whose telephone number is 571-272-8142. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Eileen O'Hara can be reached 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Chun Dahle, Ph.D. (formerly Chun Crowder)
Patent Examiner
August 6, 2008

/Maher M. Haddad/
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Primary Examiner,
Art Unit 1644